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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,322	04/02/2001	Matthew Marton	9301-136	8604
20583	7590	06/15/2005		EXAMINER
JONES DAY				MARSCHEL, ARDIN H
222 EAST 41ST ST				
NEW YORK, NY 10017			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/823,322	MARTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 06 June 2005.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-22 and 64-74 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 12-21 is/are allowed.

6)  Claim(s) 1,11,22 and 64-74 is/are rejected.

7)  Claim(s) 8-10 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. (1 copy).  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date . 5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' submission, filed 6/6/05, has been entered. Due to the newly applied rejections as summarized below, the finality of the Office action, mailed 8/11/04, is hereby withdrawn. The Notice of Appeal, filed 11/10/04, is also deemed moot.

Applicants' arguments, filed 6/6/05, have been fully considered and they are deemed to be persuasive to overcome previous rejections of record. Therefore, applicants have completely met their response burden as of 6/6/05 regarding responding to the Final action, mailed 8/11/04. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Unfortunately, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Due to the indication of allowability of claim 12 the specie election is hereby withdrawn regarding claims 13-18 and examination is extended to include all species within claims 12-21 as set forth in the Office action, mailed 12/12/02, within the elected Group I therein, which was elected in applicants' response, filed 2/3/03.

### **NON-STATUTORY SUBJECT MATTER**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 11, and 64-74 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Consideration of the "Computer-Related Inventions" section of the MPEP at section 2106, Part IV, subpart B, has revealed that the instant claims are directed to

non-statutory subject matter without requiring performance of a result outside of a computer or representing some type of physical transformation which is concrete or tangible. Thus, the manipulation of data or conversion of data, in this case drug specificity evaluation, is the claimed subject matter without any physical transformation outside of a computer or representation of a physical activity. For example, it is well known that a software program may output results to a computer file and not display it, for example, outside of the computer, thus is non-statutory subject matter. The above instant claims also lack statutory subject matter due to being directed to nonfunctional descriptive material since the claims lack performance or control of a physical transformation. Additionally, applicant(s) may wish to argue that the methods are directed to a practical invention. Consideration of the MPEP at section 2106, Part IV, subpart B, sub-subpart 2, reveals that such a practical invention type requires the production of a useful, concrete, and tangible result which is reasonably interpreted as at least some physical transformation or result or representation of such a physical transformation thereof as required for statutory subject matter. Methods per se as instantly claimed subject matter are reasonably deemed a manipulation of data for such methods, without any physical transformatin, that is, concrete or tangible, requirement. It is noted that the practical invention requirement is directed to a required combination of a useful, concrete, and tangible result which supports this rejection if only one or more of these criteria fail to be met in the claimed subject matter. It is noted that instantly pending claims which are reasonably interpreted as requiring physical transformation(s) or representation thereof are not rejected hereinunder, such as claims

which specifically contain a step of measuring. Certain claim limitations cite measurements, however, such measurements are reasonably deemed to be data and not requiring a measuring action step per se.

#### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11 and 22 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Goldenberg (P/N 5,332,567).

Goldenberg discloses the detection and treatment of infections via targeting diagnostic or therapeutic agents in the title and abstract. A variety of measurement methods are described in column 8, line 52, through column 16, line 4, including MRI imaging, immunostaining, radiolabeling, etc. wherein various antibodies are imaged as to binding to targeted sites vs. non-targeted sites. The goal is to produce a therapeutic index which is evaluated as disclosed in column 3, lines 41-58, wherein a ratio of target to non-target localization is disclosed. These measurements and the resultant ratio evaluation anticipates such measurements and specificity ratio for at least  $n = 1$  as set forth in instant claims 11 and 22.

## CLAIM OBJECTIONS

Claims 8-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 12-21 are allowable.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 9, 2005

*Ardin H. Marschel 6/9/05*  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER